

**REMARKS/ARGUMENTS**

Reconsideration is requested. Claims 1-16 are pending. Responsive to the Office Action of March 3, 2006, the Examiner's comments and the cited art have been noted and studied. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

Independent claims 1 and 15 have been amended to recite the "channel of the penetration member has a distal end of a predetermined volume" and that "the fluid flow regulator is disposed adjacent to the distal end of the channel of the penetration member." Support for these amendments is at, for example, paragraphs 00034 and 00040 and FIGs. 4 and 5 of the original disclosure. Accordingly, dependent claims 5 and 6 have been amended to clarify that the referenced diameter is at the distal end of the channel.

It is respectfully submitted that the amendments above are supported by the specification, claims, abstract of the disclosure, and drawings as originally filed, and that no new matter has been added.

**Claim Rejections under 35 U.S.C. §102**

The subject matter of claims 1-7, 12, 15 and 16 was rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,080,116 to Erickson et al. (hereinafter "Erickson").

Erickson, as understood, describes an apparatus for collecting interstitial fluid that includes a capillary tube retained within a hollow needle (see, for example, col. 6, lines 30-41 and col. 10, lines 26-33 of Erickson). Fluid is drawn into the capillary tube, but not the hollow needle (see, for example, col. 7, lines 34-38 and col. 10, lines 38-42 of Erickson). Reference to FIGs. 2, 3, 5, 4 and 7 of Erickson makes it clear that the capillary tube (element 12 and 12') into which fluid is drawn extends beyond the distal end opening of the hollow needle (element 42 and 42'), therefore precluding the hollow needle from having any free volume into which fluid could flow.

Independent claims 1 and 15, as amended, recite that the "channel of the penetration member has a distal end of a predetermined volume" and that "the fluid flow regulator is disposed adjacent to the distal end of the channel of the penetration member." In other words, the fluid flow regulator of the present invention does not extend beyond the distal end opening of the penetration member, as in the device of Erickson. Moreover, fluid must

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inherently first flow through the predetermined volume of the distal end of the penetration member before entering the fluid-flow regulator. The configuration of claims 1 and 15, as amended, is particularly beneficial in a extracting bodily fluid sample and clearly distinguished over the configuration of Erickson (see, for example, paragraph 00034 of the present disclosure).

For at least the foregoing reasons, Applicants respectfully submit that independent claims 1 and 15, as amended, are not anticipated or obvious over Erickson. Since dependent claims 2-7, 12 and 16 depend from and further limit their respective independent claims, they are allowable for at least the same reasons.

#### Claim Rejections under 35 U.S.C. §103

The subject matter of dependent claims 8 and 13 was rejected as obvious under 35 U.S.C. §103(a) over Erickson in view of U.S. Patent No. 5,354,537 to Moreno (hereinafter "Moreno").

Moreno was cited for teachings related to bores that decrease in diameter and the use of stainless steel. Applicants submit that Moreno does not cure the deficiencies of Erickson noted above and that dependent claims 8 and 14 are allowable for at least the same reasons as discussed above with respect to the rejection of claim 1.

The subject matter of dependent claim 9 was rejected as obvious under 35 U.S.C. §103(a) over Erickson in view of U.S. Patent No. 5,893,834 to Duchamp (hereinafter "Duchamp").

Duchamp was cited for teachings related to channels with step-like sections. Applicants submit that Duchamp does not cure the deficiencies of Erickson noted above and that dependent claim 9 is allowable for at least the same reasons as discussed above with respect to the rejection of claim 1.

The subject matter of dependent claim 10 was rejected as obvious under 35 U.S.C. §103(a) over Erickson. The deficiencies of Erickson with respect to independent claim 1 are discussed above. Therefore, Applicants submit dependent claim 10 is allowable for at least the same reasons as discussed above with respect to the rejection of claim 1.

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The subject matter of dependent claims 11 and 12 was rejected as obvious under 35 U.S.C. §103(a) over Erickson in view of U.S. Patent No. 6,200,277 to Kensey (hereinafter "Kensey")

Kensey was cited for teachings related to anti-thrombogenic coatings. Applicants submit that Kensey does not cure the deficiencies of Erickson noted above and that dependent claims 11 and 12 are allowable for at least the same reasons as discussed above with respect to the rejection of claim 1.

### CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and Applicants earnestly solicit early examination on the merits and issuance of a Notice of Allowance. Should the Examiner believe that any additional information or amendment is necessary to place the application in condition for allowed, he is urged to contact the undersigned Attorney via telephone at 408 956-4790, or facsimile number 408 956-4404.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Johnson & Johnson).

Respectfully submitted,

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